

K091471

Cartagloves S.A.

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Telephone: +57-1-213-9702 Fax: +57-1-213-9709

Premarket Notification 510(k)

Powder-Free Vinyl Examination Glove

21.0 Summary

[1] 510(k) Summary of Safety and Effectiveness Information

OCT 15 2009

[2] Submitter: Cartagloves S.A.
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Cartagena, Colombia
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Contact: Sam Kao
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Date: May 11, 2009

[3] Trade name: (Multiple private labels)
Common name: Powder-Free Examination Glove, Vinyl Synthetic
Classification name: Patient examination gloves, powder-free
(per proposed 21 CFR §880.6250)

[4] The predicate device, Glormed International's powder-free vinyl exam glove, listed on 510(k) K983494, is a Class I, powder-free vinyl exam glove 80LYZ that meets all of the requirements of ASTM D 5250-06, "*Standard Specification for Poly(vinyl chloride) Gloves for Medical Application.*"

[5] The powder-free vinyl exam glove meets the current specifications of ASTM D 5250-06, "*Standard Specification for Poly(vinyl chloride) Gloves for Medical Application.*"

[6] A patient examination glove is a medical device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner against potentially infectious materials.

[7] Applicant's device comparison with FDA required technological characteristics:

<u>Characteristics</u>	<u>Standard</u>
Dimensions	Meets ASTM D 5250-06
Physical Properties	Meets ASTM D 5250-06
Freedom from pinholes	Meets ASTM D 5250-06 and ASTM D 5151-99
Powder Free	Meets ASTM D 6124-06 and ASTM D 5250-06

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Biocompatibility: (based on ISO 10993)

Cytotoxicity – Agar Diffusion	Passed
Primary Skin Irritation	Passed
Repeated Patch Dermal Sensitization	Passed

Measured Parameter of Applicant Device Compared to Standard:

ASTM D5250 / ASTM D 6124 Requirement		Applicant Device Specification	
Width (mm)			
Small	85	85 +/- 5	
Medium	95	95 +/- 5	
Large	105	105 +/- 5	
X-Large	115	115 +/- 5	
Length (mm) – all sizes	230 minimum	250 +/- 10	
Thickness (mm) – all sizes			
Finger	0.05 minimum	0.05 minimum	
Palm	0.08 minimum	0.1 minimum	
Physical Testing			
Tensile Strength		Before Aging	After Aging
(in MPa)	9 minimum	9 min	9 min
Ultimate Elongation			
(in %)	300% minimum	300% min	300% min
Water Leak Test	AQL 2.5, Level I	AQL 2.5, Level I	

Both its intended use and physical characteristics is equivalent to legally marketed vinyl powder-free examination gloves. It is substantially equivalent to gloves approved as Glormed International's vinyl powder-free glove K983494.

- [8] The performance test data that support a determination of substantial equivalence are described above in Section 7.
- [9] Clinical data are not needed for examination gloves.
- [10] (Multiple private labels) Powder-Free Vinyl Examination Glove is safe and effective and will perform according to glove performance standards referenced in Section 7 above, thereby meeting ASTM D5250 and D6124 standards, FDA requirements, pinhole AQL requirement, and labeling claims for the product. Consequently, this patient examination glove is substantially equivalent to currently marketed patient examination gloves.
- [11] This summary will include any additional safety and effectiveness information reasonably deemed necessary by FDA.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-0609
Silver Spring, MD 20993-0002

Cartagloves S. A.
C/O Mr. Sam Kao
Project Manager
KalMed Supply, Incorporated
2700 North Main Street, Suite 820
Santa Ana, California 92705

OCT 15 2009

Re: K091471

Trade/Device Name: Vinyl Patient Examination Glove, Powder-Free
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: September 9, 2009
Received: September 15, 2009

Dear Mr. Kao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

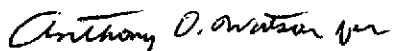
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Powder-Free Vinyl Examination Glove

3.0 Indications for Use Statement:

Indications for Use

510(k) Number (if known): K091471

Device Name: Vinyl Patient Examination Glove, Powder-Free

Indications For Use:

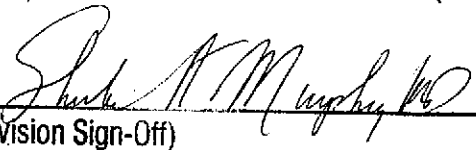
Based upon 21 CFR §880.6250 "Patient examination glove, powder-free"

A patient examination glove is a medical device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner against potentially infectious materials.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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